JUN 2 5 2001

510 (k) SUMMARY

21 CFR Subpart 807.92

Reason for 510(k): Introduction of new device

Submitter Identification:
Duoject Medical Systems Inc.
50, rue de Gaspé, Complexe B-5
Bromont, QC, Canada
J2L 2N8

Establishment Registration Number: 9613744

Contact: Daniel MacDonald
Telephone: 450-534-3666
Fax: 450-534-3700

Name of Device:

Classification Name: Vial access device
Device Trade Name: Inter-Vial
Common Name: Vial adaptor

Classification:

Name: 21CFR 880.5440 Fluid transfer set
Class: II
Panel: 80, General Hospital

Predicate Devices:

Phaseal™ Vial Adapter (K963012)
Mixject Dispensing Pin/with detachable Vial Adapter (K963583)
Vial-Mate™ Reconstitution Device (K973654)
Hypo® Safety Cartridge Syringe (K936040/S2)

Device Description:

The Duoject "Inter-Vial Admix System" transfer device is a sterile, single use device consisting of three sub-assemblies:

- A clear plastic receptacle for a drug vial (Vial Socket)
- A clear plastic receptacle for a syringe or cartridge (Syringe Socket)
- A transfer assembly with two needles or spikes.

A diluent filled cartridge type or standard piston syringe is connected into the syringe socket.
A lyophilized or other drug vial is connected into the vial socket.
The assembly is activated to mix the contents of the two into the syringe.

The system accommodates several syringe sizes (2 ml to 100 ml) and vial sizes (11 to 20 mm finishes).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2001

Mr. Daniel MacDonald
Director of Engineering
Duoject Medical Systems, Incorporated
50 Rue DE Gaspe Complex B-5
Bromont, QC,
CANADA

Re: K010703
Trade/Device Name: Inter-Vial
Regulation Number: 880.5440
Regulatory Class: II
Product Code: LHI
Dated: April 9, 2001
Received: April 17, 2001

Dear Mr. MacDonald :

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010703

Device Name: Inter-Vial

Indications For Use:

The Inter-Vial is intended to transfer and mix drugs and diluents into a syringe.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE AS NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010703